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| APPLICATION NO.                                                                                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--------------------------------------------------------------------------------------------------------------|-------------|----------------------|----------------------------------|------------------------|
| 10/642,998                                                                                                   | 08/18/2003  | John D. Hatlestad    | GUID.058PA                       | 2963                   |
| 51294 7590 10/01/2008<br>HOLLINGSWORTH & FUNK, LLC<br>8009 34TH AVE S.<br>SUITE 125<br>MINNEAPOLIS, MN 55425 |             |                      | EXAMINER<br>MUSSELMAN, TIMOTHY A |                        |
|                                                                                                              |             |                      | ART UNIT<br>3714                 | PAPER NUMBER           |
|                                                                                                              |             |                      | MAIL DATE<br>10/01/2008          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/642,998

**Applicant(s)**

HATLESTAD ET AL.

**Examiner**

TIMOTHY MUSSELMAN

**Art Unit**

3714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14 and 35-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### ***DETAILED ACTION***

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2008 has been entered, and claims 1-12, 14, and 35-46 are pending. Claims 13, 15-34, and 47-96 have been cancelled previously.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

**Claims 1-12, 14, and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (US 5,520,176) in combination with Mazer et al. (US 2004/0133079) and 'Aircraft Noise and Sleep Disturbance: Final Report', prepared by the Civil Aviation Authority London on behalf of the Department of Trade, August 1980.**

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**Regarding claims 1, 14, and 35-36, and 46,** Cohen discloses a system and methods for sleep quality data collection and analysis utilizing various measured physiological parameters. See col. 2: 33-59. Cohen fails to teach of utilizing non-physiological parameters in the research process. However, a *research* study conducted by the Civil Aviation Authority London published in 1980 pertains explicitly to this very subject. See page two, in the report summary, wherein it is described how aircraft noise was *measured* in various London neighborhoods on aircraft approach paths to the two main London airports in order to better understand how the noise interfered with the *sleep processes* of residents. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate background noise measurements (i.e. non-physiological parameter measurements) in the manner of the 1980 CAA *sleep quality research* project, into the *sleep research* System of Cohen, in order to expand the usefulness of the research system of Cohen to include cause and effect data pertaining to sleep problems.

Cohen additionally fails to teach wherein the collection and storing of sleep quality data occurs on the implantable device, and wherein the implantable device performs the evaluation, and also wherein the non-physiological data is collected external to the patient and transmitted to the implantable device (claims 36 and 46). However, Mazer discloses an implantable device utilized for research purposes that measures various parameters. See paragraphs 0035-0036. This citation describes an implantable analysis system, wherein the data can be collected, stored, and processed internally, externally, or transmitted between internal and external system components. It also discloses wherein other data involved in the analysis can be transmitted to the internal implantable device (algorithms, expert knowledge, etc.). It would have been obvious to one of ordinary skill in the art at the time of the invention to include such a distributed sensory and processing system, and particularly to have the processing occur internally to the patient, to improve the product in a manner as taught by Mazer, by allowing the device to process data and thus reducing the need for frequent external data analysis by a human (i.e. the device would transmit a report, rather than simply raw data).

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**Regarding Claims 2-6 and 8-12**, Cohen further discloses the detection and determination of metrics pertaining to; cardio-vascular conditions (**Claim 2**), see col. 6: 12-20; respiratory and disordered breathing conditions (**claims 3, 11, 39, and 43**), see col. 4: 3-10 and col. 4: 41-45; muscle system and movement disorder conditions (**claims 4, 12, 40, and 44**), see col. 8: 38-45; blood chemistry conditions (**claim 5**), see col. 5: 33-35; nervous system conditions (**claim 6**), See col. 8: 38-54; contextual conditions (**claim 8**), see the provided citations for claims 2-6; and data pertaining to sleep stages and sleep disruptions (**claims 9-10 and 37-38**), See col. 7: 20-25.

**Regarding claim 7**, the detection of environmental conditions (e.g. background noise) for sleep research is an obvious variation of Cohen in view of the CAA report as described above with regard to claim 1.

**Regarding claims 41-42**, Cohen further discloses determining and trending the measured sleep quality metrics over time. See col. 3: 17-37.

### ***Response to Arguments***

Applicant's arguments dated 6/19/2008 have been fully considered, but are moot in view of the new grounds of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./  
Acting Examiner of Art Unit 3714

/Robert E Pezzuto/  
Supervisory Primary Examiner  
Art Unit 3714